



10-02-06

TFW
1621
CASE 4-31153A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 72727207745
Express Mail Label Number

September 29, 2006
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1621

ACEMOGLU ET AL.

Examiner: Shippen, Michael L

APPLICATION NO: 10/089,038

FILED: MARCH 25, 2002

FOR: PROCESS FOR PHENYLACETIC ACID DERIVATIVES

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

COMMUNICATION REQUESTING WITHDRAWAL OF THE
HOLDING OF ABANDONMENT

Sir:

This paper is being sent to request that the above-identified application, which became abandoned for failure to file a response to the Official Action, dated January 5, 2004, be withdrawn from abandonment and put back in pending status.

As is clear from the enclosed copies of the stamped return receipt postcard and the Express Mail label, an Amendment and Petition for Extension of Time were timely received by the U.S. Patent and Trademark Office (PTO) on July 6, 2004, July 5, 2004 being a holiday. The timely receipt of said papers by the PTO as also confirmed upon review of the contents of the file in the public "PAIR". Accordingly, Ms. Dolores DeCarmine called the PTO Inventor's Assistant Center on September 5, 2006 and was informed by the person checking the records that the Amendment and Petition for Extension of Time were put in the wrong case folder (**Application No. 10/080,038**), thereby causing the abandonment of the subject application, and were just recently moved to the right case folder (**Application No. 10/089,038**).

In any event, enclosed are copies of the Amendment and Petition for Extension of Time which were received by the PTO on July 6, 2004.

In view of the foregoing, it is clear that the above-identified application became abandoned as a result of **an administrative breakdown at the PTO**. Accordingly, it is respectfully requested that the status of the above-identified application be changed from "abandoned" to pending.

If any fee is believed to be necessary, the Commissioner is hereby authorized to charge Deposit Account No. 19-0134 in the name of Novartis.

Respectfully submitted,



Peter J. Waibel
Attorney for Applicants
Reg. No. 43,228

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7951
Encls.:

Date: *September 29, 2006*

Case No. 4-31133A
Application No. 10/1069,038
Mailing Date: July 6, 2004
Due Date: April 5, 2004
Express Mail No.: EV 540563PY US

The Patent & Trademark Office acknowledges, and has stamped hereon the date of receipt of the items checked below:

- ☒ Amendment/Response/Letter - Fee \$ (6296)
☐ Appln. Filing Papers - Fee \$
☐ PCT National Stage
☐ Provisional Application
☐ RCE ☐ DIV ☐ CONT ☐ CIP
☐ Specification
☐ Executed/Unexecuted Decl. - Fee \$
☐ Missing Parts/Missing Rec. Under Continued Prosecution
☐ Preliminary Amendment
☐ Claim of Priority ☐ Certified Copy(s)
☐ Amendment After Final
☐ Notice of Appeal - Fee \$
☐ Appeal Brief - Fee \$
☐ Issue Fee Payment \$
☐ Assignment Rec. Req. - Fee \$
☐ Formal Drawings Pg's
☐ IDS Pg's - Fee \$
☐ PTO-1449 Form Pg's
☒ Pet. for Ext. of Time - Fee \$ 950
☐ Application Data Sheet
☐ Seq. Listings Pg's/Seq. Disk
☐


Initials



EV 540156384 US

**EXPRESS
MAIL**Customer Copy
Label 11-F, June 2002

UNITED STATES POSTAL SERVICE®

Post Office To Addressee

ORIGIN (POSTAL USE ONLY)

PO ZIP Code 07932	Day of Delivery <input checked="" type="checkbox"/> Next <input type="checkbox"/> Second <input type="checkbox"/>	Flat Rate Envelope <input type="checkbox"/>
Date 7/6/04	<input type="checkbox"/> 12 Noon <input type="checkbox"/> 3 PM	Postage \$ 13.65
Mo. Day Year 4 09	Military <input type="checkbox"/> 2nd Day <input type="checkbox"/> 3rd Day	Return Receipt Fee \$
Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Int'l Alpha Country Code	COD Fee Insurance Fee
Weight 3 lbs. 0 oz.	Acceptance Clerk Initials 17	Total Postage & Fees \$ 13.65
No Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday		

DELIVERY (POSTAL USE ONLY)

Delivery Attempt	Time	Employee Signature
Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	
Delivery Attempt	Time	Employee Signature
Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	
Delivery Date	Time	Employee Signature
Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	

CUSTOMER USE ONLY

METHOD OF PAYMENT:

Express Mail Corporate Acct. No.

X079952

FROM: (PLEASE PRINT)

PHONE

NOVARTIS
ONE HEALTH PLAZA
BLOG 430
EAST HANOVER

NJ 07936-1016

TO: (PLEASE PRINT)

PHONE

USPS STOP AMENDMENT
COMMISSIONER FOR PATENTS
PO BOX 1450
ALEXANDRIA, VA 22313-1450

PRESS HARD.

You are making 3 copies

FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.com





CASE 4-31153A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 540156384 US

Express Mail Label Number

July 6, 2004

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

EXAMINER: M. L. Shippen

ACEMOGLU ET AL.

APPLICATION NO: 10/089038

ART UNIT: 1621

FILED: MARCH 25, 2002

FOR: PROCESS FOR PHENYLACETIC ACID DERIVATIVES

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

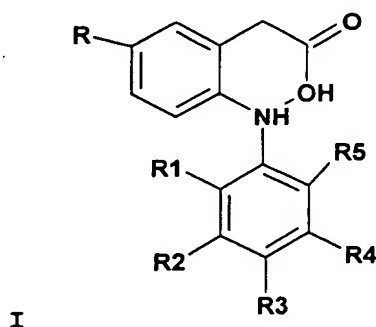
This amendment and attached papers are responsive to the Office Action mailed on January 5, 2004 and are being filed by Express mail on July 6, 2004. July 5, 2004 being a holiday, the Applicants file these papers and herein request a three month extension of time. The Commissioner is hereby authorized to charge the fee for \$950.00 for such extension and any additional fees that are properly assessable for the application to Deposit Account No. 19-0134 in the name of Novartis.

The amendments to the claims begin on page 2 of this response comments begin on page 5 in the section entitled "REMARKS".

AMENDMENTS TO THE CLAIMS

Listing of claims:

1. (currently amended) A process for the production of a compound of Formula I, or a pharmaceutically acceptable salt thereof, or a pharmaceutically acceptable prodrug ester thereof,



wherein R is methyl or ethyl;

R1 is chloro or fluoro;

R2 is hydrogen or fluoro;

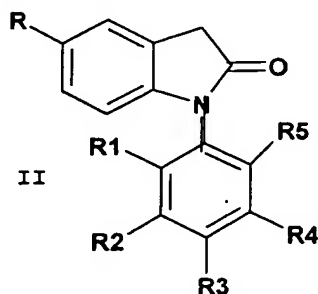
R3 is hydrogen, fluoro, chloro, methyl, ethyl, methoxy, ethoxy, or hydroxy;

R4 is hydrogen or fluoro; and

R5 is chloro, fluoro, trifluoromethyl or methyl,

provided that R1, R2, R3, R4 and R5 are not all fluoro when R is ethyl and R3 is H;

comprising cleaving a lactam of formula II

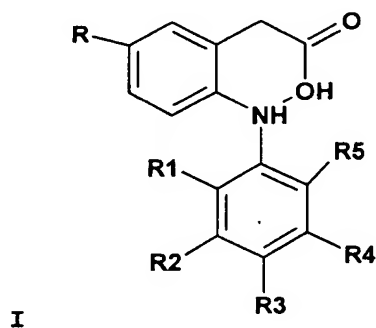


wherein the symbols are as defined above with a base; and in the above process, if ~~desired~~optionally, temporarily protecting any interfering reactive groups and then isolating the resulting compound of ~~the invention~~formula I; and, if ~~desired~~optionally, converting the free carboxylic acid of the compound of formula I into a pharmaceutically acceptable ester derivative

thereof; and ~~if desired~~ optionally, converting the free acid of formula I into a salt or a resulting salt of formula I into the free acid or into another salt.

2. (cancelled)

3. (currently amended) A process for the preparation of a compound of Formula I as defined in claim 1 ~~[[.]]~~



which comprises one or more of processes a) to n) as defined in claim 2 ~~and optionally~~ or a process according to claim 1.

4. (original)

5. (original)

6. (original)

7. (original)

REMARKS

The Examiner has objected claims 3-6 under 37 C.F.R. § 1.75(c) as allegedly being in improper form for being multiple dependent claims which do not refer to more than one claim in the alternative. Accordingly, the Applicants have amended claim 3 to refer to more than one claim now using the alternative language "or". Claims 4, 5, and 6 are now properly dependent upon claim 3 which, in its amended form, is a proper multiple dependent claim. Therefore, the Applicants respectfully request that the Examiner withdraw the rejection of claims 3-6 on these grounds.

The Examiner has rejected claim 1 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out the invention due to the use of the phrase "if desired" for various process steps which are meant to be referred to as optional steps. The Applicants have amended the language of claim 1 so that all instances of the use of "if desired" have been replaced with the word "optionally". The deleted language, "if desired", is used in the original United Kingdom and European claims in the priority application. The use of the word "optionally" reflects the original intent of the Applicants in more proper United States practice language. The Applicants therefore respectfully request that the Examiner withdraw the rejections upon these grounds.

The Examiner has also rejected claim 1 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out the invention due to the use of the phrase "compound of the invention". The Applicants have amended claim 1 to delete such language and replace it with "compound of formula I". In this way, the Applicants seek to highlight the compounds corresponding to formula I which result from the process described in claim 1 and reflected in the language on page 1 in lines 1-14 of the Specification. The Applicants therefore respectfully request that the Examiner withdraw the rejections upon these grounds.

The Examiner has rejected claim 2 as allegedly being drawn to an improper Markush grouping of processes. Claim 2 claims alternative methods of preparation of 2-aryl-amino-arylacetic acids (COX-2 Inhibitors). An overview of synthetic methodologies of the processes claimed in claim 2 is included in the Specification on page 11. As such, the processes steps claimed in claim 2 are well described and identified as producing intermediates in the production of the compound of formula I which has specific COX-2 inhibitory activity. The Applicants assert that the synthetic methodology flowchart on page 11 of the Specification establishes the requisite unity and is

reflected in the process steps claimed in claim 2. Therefore, the Applicants respectfully request that the Examiner withdraw the rejection of claim 2 upon these grounds.

The Examiner has rejected claim 7 as allegedly being drawn to an improper Markush grouping of compounds. The Examiner states that the members of the Markush group do not belong to a recognized class or that they do not possess common use or have separate uses in distinct processes. The Applicants assert that claim 7 claims compounds which may be used in the synthesis of 2-aryl-amino-arylacetic acids (COX-2 Inhibitors) that are exemplified in a compound of formula I as claimed in claim 1. The Overview of synthetic methodologies on page 11 of the Specification establishes that the compounds claimed in claim 7 are compounds which either a) have COX-2 inhibitory activity individually and/or b) are compounds which may be used as intermediates in synthetic methodologies which ultimately lead to a production of a compound of formula I as shown on page 11 of the Specification. The Applicants assert that the synthetic methodology flowchart on page 11 of the Specification exemplifies the required commonality for the Markush grouping of claim 7. Therefore, the Applicants respectfully disagree with the Examiner's rejections and characterization of the compounds of claim 7 and request that the Examiner withdraw the rejection of claim 7 on these grounds.

The Examiner has rejected claims 1 and 2 under 35 U.S.C. § 103(a) over WO 99/11605 and U.S. Patent No. 3,558,690. The Examiner states that the Applicants' claimed process affords the products of the teachings of the prior art and that the use of a new starting material in an otherwise old process is considered obvious. The Examiner further states that the Applicants' products are "admittedly well known useful products" and cites Example 38 of WO 99/11605 and compounds of formula III (a) of US Patent No. 3,558,690 in order to attempt to make this point. The Applicants respectfully disagree with the Examiner and request that the rejection be withdrawn. Formula I as disclosed and claimed in the present Application provides that R1, R2, R4 and R5 are not all fluoro when R is ethyl and R3 is hydrogen (please see claim 1, page 46, line 12 and page 1 line 14 of the Specification). Therefore, a compound of formula I as disclosed and claimed in the present Application specifically excludes the starting compounds and the products of Example 38 and the claims of WO 99/11605 and also excludes the compounds of formula III (a) as disclosed in US Patent No. 3,558,690. The Applicant disagrees that one would be motivated by the prior art teachings to make the compounds of the present invention via the process claimed in claims 1 and 2. In opposition to the Examiner's statements that the products are well-known in the art, the specific utility of the compounds as either COX-2 inhibitors or intermediates in the synthesis of such compounds is new and not disclosed in the prior art. There is no suggestion that one could make the COX-2 inhibitors of the present invention via the processes claimed in the present application. The exclusion of compounds in Example 38 of

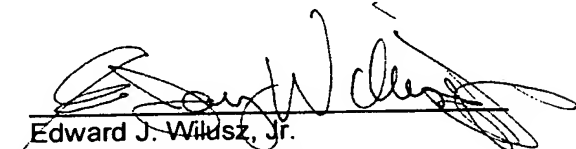
WO 99/11605 and US 3,558,690 exemplifies the fact that such compounds are newly identified and claimed in the present Application. The Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1 and 2 on these grounds.

The Examiner has rejected claim 7 under 35 U.S.C. § 103(a) over WO 99/11605 and U.S. Patent No. 3,558,690. The Examiner states that the compounds of the present invention as claimed in claim 7 are homologues of the class of compounds of the references. The Applicants respectfully disagree with the Examiner and request that the rejection be withdrawn. As discussed above, for the rejection of claim 1 and 2, the prior art references do not disclose and claim that the specific starting materials or products may be used as intermediates in the preparation of the COX-2 inhibitors of the present invention. This includes the compounds of claim 7. The Applicants dispute that the compounds of claim 7 are homologues of the prior art disclosures. The community of properties associating the compounds of claim 7 in the present Application identifies that they are synthetic precursors to COX-2 inhibitors claimed in formula I. The compounds of formula I differ by more than a methylene linkage over the prior art cited by the Examiner. The compounds of the invention differ in the identities of from two to five substituents over the prior art as shown in claim 1 on page 46 in line 12. The compounds of claim 7 differ over the prior art by having different groups on both of the phenyl rings of the compounds of the invention. The Applicants assert that the compounds of the present invention are not taught by the prior art for the use claimed by the Applicants. The compounds claimed in the present application are in fact specifically selected outside of the prior art because they have been determined by the Applicants to be useful for preparation of the COX-2 inhibitor reaction products claimed in the present application. The Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1 and 2 on these grounds.

In light of the foregoing amendment and remarks the Applicants believe the Application is in condition for allowance and respectfully request early notice to that effect. If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7960


Edward J. Wildsz, Jr.
Attorney for Applicant
Reg. No. 52,370

Date: July 6, 2004



CASE 4-31135A

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 540156384 US

Express Mail Label Number

July 6, 2004

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ACEMOGLU ET AL.

APPLICATION NO: 10/089038

FILED: March 25, 2002

FOR: PROCESS FOR PHENYLACETIC ACID DERIVATIVES

EXAMINER: M. L. Shippen

ART UNIT: 1621

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME

Sir:

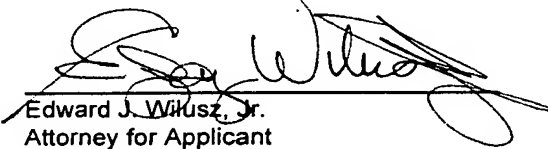
The Office Action of January 5, 2004 has a shortened statutory time set to expire on April 5, 2004. A three-month extension is hereby requested pursuant to 37 CFR §1.136(a).

Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$950 for payment of the extension fee. An additional copy of this paper is here enclosed. The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080

Date: July 6, 2004


Edward J. Wilusz, Jr.
Attorney for Applicant
Reg. No. 52,370
Phone No. (862) 778-7960